Aventis Pasteur

- URGENT VACCINE RECALL-

Voluntary Recall of Imovax â Rabies, Rabies Vaccine (Human Diploid Cell)
Lot Numbers X0667-2 and X0667-3 (Expiration date 6/24/06);
W1419-2 and W1419-3 (Expiration date 12/06/05)

April 5, 2004

Dear Health Care Provider:

Aventis Pasteur is committed to providing our customers with vaccines of the highest purity, potency and safety. Consistent with our commitment, Aventis Pasteur is contacting all customers who have received Imovax® Rabies, Rabies Vaccine (Human Diploid Cell), lots X0667-2, X0667-3, W1419-2 and W1419-3, to inform them of an urgent vaccine recall.

A recent Quality Assurance test of Imovax® Rabies Vaccine revealed the presence of non-inactivated Pitman-Moore virus (the attenuated vaccine strain) in a single product lot. This lot was not distributed. As a precautionary measure, Aventis Pasteur has decided to initiate a voluntary recall of all lots produced during the same time period, even though these related lots have passed all release tests. Of the lots produced during the time period, only four lots (X0667-2, X0667-3, W1419-2 and W1419-3) were distributed to our U.S. customers.

If you have any remaining doses of these four lots, **DO NOT USE THESE DOSES.** We strongly recommend that you follow the procedures outlined in this recall letter and in the attached *Instructions For Complying With Recall*. If you want additional quantities of these recall communication materials or if you have any questions about product return procedures, please contact us at 1-800-335-1349 and we will be glad to assist you.

We have also enclosed a *Medical Opinion from Aventis Pasteur Regarding Management of Patients* to provide further information and guidance. Should you have any questions, please call the Aventis Pasteur Medical Information Services Department at 1-800-835-3587.

If any patients who have received the recalled product have experienced adverse events, please call us at 1-800-835-3587 to advise us of the nature of the event and contact the U.S. Department of Health and Human Services Vaccine Adverse Event Reporting Systems (VAERS). Reporting forms and information about reporting requirements or completion of the form can be obtained from VAERS through a toll-free number 1-800-822-7967.

This voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Please accept our apologies for any inconvenience we may have caused. You are a valued Aventis Pasteur customer and we greatly appreciate your cooperation.

Very truly yours,

Michael Decker

Michael D. Decker, MD, MPH
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